K043052

NOV 2 4 2004

Smith & Nephew, Inc.
Summary of Safety and Effectiveness
TriGen Hindfoot Fusion Nail

Contact Person and Address
Janet Johnson Akil
Director, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116
(901) 399-5153

Date of Summary: November 4, 2004

Name of Device: TriGen Hindfoot Fusion Nail
Common Name: Intramedullary Fixation Rod

Device Description
The TriGen Hindfoot Fusion Nail (HFN) is an intramedullary nail used for fixation of the ankle and hind foot. The TriGen HFN nails are made from titanium alloy conforming to ASTM F 1472 and are used with existing bone screws.

Device Classification
21 CFR 888.3020 Intramedullary fixation rod – Class II

Mechanical and Clinical Data
A review of the mechanical test data indicated that the TriGen HFN is equivalent to devices currently used clinically and is capable of withstanding expected *in vivo* loading without failure.

Indications for Use
The TriGen Hindfoot Fusion Nail (HFN) is indicated for degeneration, deformity, or trauma of both the tibiotalar and talocalcaneal articulations in the hindfoot; tibiocalcaneal arthrodesis; combined arthrodesis of the ankle and sub-talar joints; avascular necrosis of the ankle and sub-talar joints; failed total ankle replacement with sub-talar intrusion; failed ankle arthrodesis with insufficient talar body; rheumatoid arthritis; severe deformity secondary to untreated talipes equinovarus or neuromuscular disease; and severe pilon fractures with trauma to the subtalar joints. The TriGen HFN is for single use only.

Substantial Equivalence Information
The substantial equivalence of the TriGen HFN is based on its similarities in indications for use, design features, operational principles, and material composition to the following predicate devices – the Smith & Nephew, Inc. Tibia-Talus-Calcaneus Nail (K950394) and the Encore Orthopedics UltiMax Ankle Fusion Rod System (K991790).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2004

Ms. Janet Johnson Akil
Director, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K043052
Trade/Device Name: TriGen Hindfoot Fusion Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: October 4, 2004
Received: October 5, 2004

Dear Ms. Akil:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: TriGen Hindfoot Fusion Nail

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K043052